***NOT FOR PUBLICATION**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELOISE LABARRE, as surviving Spouse and Administratrix of the Estate of Edward Clyde LaBarre, Sr., Deceased,	:	Civil Action No. 06-6050(FLW)
Plaintiff,	:	**OPINION**
v.	:	
BRISTOL-MYERS SQUIBB CO., et al.,	:	
Defendants.	:	

WOLFSON, District Judge:

Plaintiff Eloise LaBarre ("Plaintiff"), as surviving spouse and administratrix of the Estate of Edward Clyde LaBarre, Sr. ("Mr. LaBarre"), brings the instant suit against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that her late husband, Mr. LaBarre, suffered fatal injuries as a result of Defendants' design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Amended Complaint ("Amended Complaint") asserts various Florida state and common law claims against Defendants, including Failure-to-Warn, Defective

Design, Manufacturing Defect and Negligence.[1] Before the Court is Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under Florida law. For the reasons that follow, Defendants' motion for summary judgment is GRANTED and all counts in the Amended Complaint are dismissed.[2]

BACKGROUND[3]

A. Plavix

Plavix is a drug that inhibits blood platelets from forming clots. The drug was initially approved by the United States Food

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[1] In her Original Complaint, Plaintiff initially asserted New Jersey state and common law claims against Defendants. Following two separate decisions rendered by the New Jersey Supreme Court in 2007, Plaintiff voluntarily dismissed those New Jersey claims and amended her Complaint to assert causes of action arising only under Florida state law. See Opinion dated December 30, 2009, pp. 2-3. Therefore, Florida law controls on this motion.

[2] Pending before this Court are related cases filed by other plaintiffs who were allegedly injured by ingesting Plavix, albeit their injuries may be different than those suffered by Mr. Mr. LaBarre in this case. In those related cases, Defendants have also filed summary judgment motions. Moreover, the Court is aware that there are numerous cases concerning Plavix brought against Defendants in other state and federal courts across the country. Because each plaintiff's personal circumstances differ, the Court's findings in this Opinion only represent the application of pertinent state law, i.e., Florida, to the facts presented in this particular case. That said, to avoid unnecessary duplication of effort in my several related cases and to conserve judicial resources, I cite to the analysis of similar legal issues in my primary filed opinion in Solomon v. BMS, Civil Action No. 07-1102 (FLW), where appropriate.

[3] The following facts are undisputed unless otherwise noted.

and Drug Administration ("FDA") for use as monotherapy, i.e., taken without another drug, in patients with recent heart attack, stroke, or diagnosed peripheral vascular disease ("PVD"). See Defs. Statement, ¶ 2. Thereafter, the FDA approved Plavix for dual therapy with aspirin, which also contains antiplatelet effects, in the treatment of patients with particular types of acute coronary syndrome ("ACS").[4] Id. at ¶ 3.

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, labeling on Plavix included certain information on that risk. The label provides:

> **PRECAUTIONS**
>
> **General**
> As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.
>
> *GI Bleeding*: PLAVIX prolongs the bleeding time. In

[4] ACS is a set of clinical signs and symptoms occurring when the heart muscle does not receive enough blood because of plaque narrowing or blocking of the arteries leading to the heart. Commonly, ACS includes, inter alia, heart attacks and irregular chest pains known as unstable angina. See, e.g., Frederick G. Kushner, et al., 2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infraction and Guidelines on Percutaneous Coronary Intervention, 54 J. Am. C. Cardiology 2205, 2212 (2009).

CAPRIE[5], PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0% vs. 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX.

* * *

Information for Patients

Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician.

* * *

ADVERSE REACTIONS

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3)[6]. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage

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[5] According to BMS, the clinical evidence for the risks of PLAVIX is derived from two double-blind trials: (i) the CAPRIE study (Clopidogrel v. Aspirin in Patients at Risk of Ischemic Events), a comparison of PLAVIX to aspirin, and (ii) the CURE study (Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events), a comparison of PLAVIX to placebo, both given in combination with aspirin and other standard therapy. See February 2002 Plavix Labeling, p.3. Plaintiff contests the accuracy of these clinical trials; those arguments will be further discussed in this Opinion.

[6] Table 3 of the labeling includes certain "incidence of bleeding."

> (0.1%), and fatal bleeding (0.2%), was the same in both groups.

See, generally, February 2002 Plavix Labeling.

B. Plaintiff Medical History

Mr. LaBarre had a history of coronary artery related health issues. Based on the record, Mr. LaBarre's first myocardial infarction, or heart attack, occurred in June 1990. See PTCA Report dated July 6, 1990, p. 1. Subsequently, an angioplasty was performed to clear his blocked coronary arteries. Id. at pp. 3-4. The next incident related to Mr. LaBarre's ACS occurred in October 2002. At that time, Mr. LaBarre presented to the emergency room with "an episode of midsternal chest pain which radiated down the right arm and shoulder." See Discharge Summary Dated November 14, 2002. Dr. Leisa Bailey, Mr. LaBarre's primary physician, in consultation with Mr. LaBarre's then-cardiologist, Dr. Leland Eaton, prescribed Plavix and nitroglycerin. See Id. Shortly after, in November 2002, Dr. Eaton performed a coronary artery bypass grafting, or a double bypass operation, on Mr. LaBarre. See Discharge Summary dated July 3, 2003, p. 2. Because of the operation, Mr. LaBarre was instructed to stop taking Plavix and even after the bypass surgery, Mr. LaBarre did not resume taking Plavix; rather, he was instructed to take aspirin alone. See Dr. Bailey Dep., T110:14-111:12.

In June 2003, Mr. LaBarre again went to the emergency room with a heart attack. See Discharge Summary dated July 3, 2003, p.

2. This time – more than seven months after his operation – Mr. LaBarre was put on Plavix and aspirin before being discharged from the hospital. Id., p. 2. Thereafter, Dr. Benjamin Craven became Mr. LaBarre's cardiologist, and between the period of July 2003 and July 2004, Dr. Craven continued to prescribe Plavix and aspirin for Mr. LaBarre . Dr. Baily kept Mr. LaBarre on dual therapy until December 2004.

In early December 2004, Mr. LaBarre bumped his head while working in his barn. See LaBarre Dep., T252:14-20. Approximately two weeks later, Mr. LaBarre suffered a severe headache and became unconscious. See Southeast Alabama Medical Center History and Physical, pp. 1-2. Mr. LaBarre was diagnosed with a "large acute subdermal hematoma," which caused brain stem damage. Id. He died on December 21, 2004. The cause of death on the Death Certificate indicated that Mr. LaBarre's Subdermal hematoma was a consequence of the Plavix therapy. See Death Cert. dated January 27, 2005.

C. Plaintiff's Amended Complaint

Because of the death of her husband, Plaintiff brings this wrongful death and survival action against Defendants, asserting product liability related causes of action, under Florida state law, for defective design, manufacturing defect, failure to warn, and negligence.[7] See Am. Compl., Count I - Count IV. Although

[7] On December 30, 2009, this Court dismissed Plaintiff's claims for negligent misrepresentation (Count V) and for violation of the Florida Unfair Deceptive Trade Practices Act

these claims are characterized differently, they essentially turn on whether Defendants adequately warned that Plavix carried a risk of bleeding complications. In that regard, Defendants argue on this motion that the learned intermediary doctrine precludes Plaintiff from suing them because the doctrine excuses drug manufacturers from warning Mr. LaBarre, individually, when these manufacturers have properly and adequately warned the prescribing physicians regarding Plavix's risks.

DISCUSSION

I. Standard of Review

Summary judgment is "proper if there is no genuine issue of material fact and if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." Pearson v. Component Tech. Corp., 247 F.3d 471, 482 n. 1 (3d Cir.2001) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)); accord Fed. R. Civ. P. 56(c). For an issue to be genuine, there must be "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party." Kaucher v. County of Bucks, 455 F.3d 418, 423 (3d Cir.2006); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In determining whether a genuine issue of material fact exists, the court must view the facts and all reasonable inferences drawn from those facts in the light most favorable to the nonmoving party.

(Count VI). See Order dated December 30, 2009.

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Curley v. Klem, 298 F.3d 271, 276-77 (3d Cir.2002). For a fact to be material, it must have the ability to "affect the outcome of the suit under governing law." Kaucher, 455 F.3d at 423. Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment.

Initially, the moving party has the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp., 477 U.S. at 323. Once the moving party has met this burden, the nonmoving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. Id.; Maidenbaum v. Bally's Park Place, Inc., 870 F.Supp. 1254, 1258 (D.N.J.1994). Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the moving party. Anderson, 477 U.S. at 256-57. "A nonmoving party may not 'rest upon mere allegations, general denials or ... vague statements...'" Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs., 982 F.2d 884, 890 (3d Cir. 1992) (quoting Quiroga v. Hasbro, Inc., 934 F.2d 497, 500 (3d Cir. 1991)). Moreover, the non-moving party must present "more than a scintilla of evidence showing that there is a genuine issue for trial." Woloszyn v. County of Lawrence, 396 F.3d 314, 319 (3d Cir. 2005). Indeed, the plain language of Rule 56(c) mandates the entry of

summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. Celotex Corp., 477 U.S. at 322.

Moreover, in deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. Credibility determinations are the province of the fact finder. Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

II. Florida Failure-to-Warn Claim

Plaintiff maintains that Defendants failed to adequately warn Mr. LaBarre's prescribing physicians of the potential for bleeding complications from taking Plavix. More specifically, Plaintiff insists that Mr. LaBarre's prescribing physicians were not warned 1) regarding the substantial risk of serious bleeding caused by taking Plavix with aspirin; and 2) that Plavix does not provide any benefit to patients who take Plavix in addition to aspirin longer than a few months. In essence, Plaintiff claims that Defendants failed to inform physicians of the true risk of bleeding and the lack of efficacy of Plavix.

Generally, under Florida law, a manufacturer of a "dangerous commodity," such as a prescription drug, has a duty to warn consumers of the known risks of using its product. Horrillo v. Cook Inc., No. 10-1537, 2012 U.S. App. LEXIS 26317, at *6-7 (11th Cir. Nov. 7, 2012) (citing Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981)). Failure to provide that warning may render the manufacturer strictly liable for any resulting harm. Id. at *7. However, in the context of prescription drugs, Florida law applies the learned intermediary doctrine, whereby the duty to warn flows from the drug manufacturer to the physician, and not the ultimate consumer. Bailey v. Janssen Pharmaceutica, Inc., 288 Fed. Appx. 597, 608 (11th Cir. 2008); Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989) ("At the outset, it is clear that the manufacturer's duty to warn of [the drug's] dangerous side effects was directed to the physician rather than the patient."); E.R. Squibb & Sons v. Fames, 697 So. 2d 825, 827 (Fla. 1997).

Under this doctrine, "[s]o long as a drug's warning to the prescribing physician is adequate, a manufacturer will not be strictly liable for failure to warn when a doctor prescribes a particular drug or fails to inform his patient of certain risks

associated with the medication."[8] Id. The underlying policy for the learned intermediary doctrine is that,

> prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Buckner v. Allergan Pharms., 400 So. 2d 820, 822 (Fla. 5th DCA 1981). Accordingly, based on the policy rationale, if an adequate warning exists, the manufacturer of the drug would not be held liable for failure to warn. See Felix, 540 So. 2d at 105.

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[8] Plaintiff implores this Court to reject the learned intermediary doctrine when examining Florida product liability laws. In so doing, Plaintiff relies on a decision rendered by the West Virginia Supreme Court in State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E. 2d 899 (W. Va. 2007), wherein the Court eliminated the learned intermediary doctrine in that state. As Plaintiff should be aware, because Florida law controls in this case, this Court, sitting in diversity, is bound to follow state law as announced by the highest court in Florida. See Nuveen Mun. Trust v. Withumsmith Brown, P.C., 692 F.3d 283, 315 (3d Cir. 2012). And, the Florida Supreme Court has long recognized the learned intermediary doctrine in the context of prescription drugs. See Felix, 540 So. 2d at 104. Ever since Felix, Florida courts have consistently applied the doctrine to pharmaceutical liability cases. See Colville v. Pharmacia & Upjohn Co. LLC, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008)(collecting cases). Accordingly, this Court has no basis to depart from established Florida law.

In order to prove strict liability based on a drug's insufficient warning, the plaintiff must establish "(1) that the warnings accompanying the [product] were inadequate; (2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and (3) that Plaintiff in fact suffered an injury by using the product."[9] Hosler v. Alcon Labs., Inc., NO. 16-60025, 2012 U.S. Dist. LEXIS 145176, at *25 (S.D. Fla. Oct. 9, 2012)(citing Colville, 565 F. Supp. 2d at 1320).

With respect to the first prong, the Florida Supreme Court has instructed that the adequacy of the warning turns on whether the "warnings were adequate to warn a physician of the possibility that [the medicine] might be causing the condition experienced" by the Plaintiff." Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990). That determination must be made through the testimony of an expert. Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007). In that regard, courts in Florida have not hesitated to dismiss cases on summary judgment when the plaintiff "failed to present an expert witness in support of her claim of inadequate warning." Paparo v. Ortho-McNeil Pharmaceutical, No. 05-81044, 2007 U.S. Dist. LEXIS 2356, at *4 (S.D. Fla. Jan. 10, 2007) (citing Haggerty v. Upjohn Co., 950 F.Supp. 1160, 1168 (S.D. Fla. 1996); MacMurdo, 562 So.2d at 683; and Felix, 540 So.2d at 104); see also

[9] For the purposes of this motion, Defendants do not dispute that Plaintiff is able to prove injury-in-fact.

Humphreys v. Gen. Motors Corp., 839 F. Supp. 822, 825 (N.D. Fla. 1993) (finding that the defendant is "permitted to rely upon the complete absence of proof of an essential element of [p]laintiff['s] case to support its motion for summary judgment"). Importantly, the Florida Supreme Court has advised that while in many instances the adequacy of warnings concerning drugs is a question of fact, this inquiry "can become a question of law where the warning is accurate, clear, and unambiguous." Felix, 540 So. 2d at 105.

On the issue of causation, Florida law requires the plaintiff to prove by a preponderance of the evidence, with "reasonable medical probability," that the drug manufacturer's alleged failure to warn was the proximate cause of Plaintiff's injury. Christopher, 53 F.3d at 1191(citing Reaves v. Armstrong World Industries, Inc., 569 So. 2d 1307, 1309 (Fla. Ct. App. 1990)). "In other words, plaintiffs must show that is 'more likely than not' that the defendant's act was a substantial factor in bringing about the injury." Christopher v. Cutter Lab., 53 F.3d 1184, 1192 (11th Cir. 1995)(quoting Gooding v. University Hospital Building, Inc., 445 So. 2d 1015, 1018 (Fla. 1984)). "A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." Reaves, 569 So. 2d at 1309.

To prove causation, the plaintiff must show that the "'failure of [a] manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is **not** the proximate cause of a patient's injury **if** the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated.'" Beale, 492 F. Supp. 2d at 1365 (S.D. Fla. 2007)(quoting Christopher, 53 F.3d at 1192)(emphasis added). Thus, "the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." Id. Moreover, Plaintiff must show that the physician would not have made the same prescribing decision with a different warning. See Levin v. Wyeth, Inc,. NO. 09-854, 2010 U.S. Dist. LEXIS 130855, at *11-12 (M.D. Fla. Dec. 10, 2010); see also Hoffmann-LaRoche Inc. v. Mason, 27 So. 3d 75, 77 (Fla. 1st DCA 2009)(finding a lack of causation because "Appellee presented no evidence from either treating physician that a differently worded warning would have resulted in either physician not prescribing Accutane for his extreme acne.").

A. Accuracy of Plavix's Warning Label

At the outset, the Court finds that, based on the record, there is evidence to support the allegation that the cause of Mr. LaBarre's death could be attributed to his Plavix therapy. See, e.g., Death Cert. dated January 27, 2005. However, the inquiry

here is not whether taking Plavix ultimately contributed to Mr. LaBarre's death, but rather, whether the learned intermediary doctrine excuses Defendants from liability based upon the policy rationale espoused by the Florida Supreme Court. Because the Court answers in the affirmative, Plaintiff's failure-to-warn claim fails.

For her failure-to-warn claim, Plaintiff essentially complains that Defendants did not adequately warn about the substantial risk of serious bleeding caused by taking Plavix with aspirin, and that Plavix loses its efficacy for patients on dural therapy for more than a few months. Indeed, Plaintiff dedicates much of her arguments to the effectiveness of Plavix.

As an initial matter, this Court finds that although Plaintiff presents various studies and articles challenging the efficacy of Plavix in certain types of patients, none of those studies are relevant to Mr. LaBarre's medical situation. For example, according to Plaintiff's expert, Dr. Moye, the Defendant-sponsored MATCH study in 2004 found that Plavix and aspirin was no better than aspirin alone in treating patients with recurrent transient ischemic stroke events. In that regard, based on an article published by the American Heart Journal, Plaintiff claims that more than 40% of Plavix use was for conditions where there was no evidence that Plavix had any effectiveness over aspirin or any effectiveness at all. See Pl.'s Ex. 16. Plaintiff credits

Defendants' aggressive marketing as the reason why physicians continue to prescribe Plavix in the absence of evidence of efficacy. See Pl. Ex. 28. Notwithstanding this position, Mr. LaBarre, however, did not suffer from transient ischemic stroke - he was placed on dual therapy because of complications stemming from ACS. Thus, this study is irrelevant to Plaintiff's claim.

In fact, the majority of the Plavix efficacy studies cited by Plaintiff are unrelated to Mr. LaBarre's personal circumstances. In one example, Plaintiff cites certain studies to show that Plavix is ineffective as post-operative treatment for coronary bypass. See Pl. Ex. 20. Mr. LaBarre was treated with Plavix in the summer of 2003 when he suffered a heart attack, not after his prior bypass surgery in November 2002. To the extent Plaintiff suggests that these studies are relevant – despite the time gap – Plaintiff has failed to link the studies' conclusions to Mr. LaBarre's circumstances. Similarly, the studies upon which Plaintiff rely regarding Plavix's ineffectiveness for patients 75 years or older has limited relevance since Mr. LaBarre was put on Plavix before he was 75 years old. Although Mr. LaBarre was 74 years old when he died, Plaintiff does not offer any expert testimony as to how those studies should have impacted Plavix's warning label, insofar as it relates to Mr. LaBarre, who was approaching 75 years of age. This is critical because as the Court has stressed previously, Plaintiff must present the testimony of an expert in order to establish the

inadequacy of a particular warning label. Beale, 492 F. Supp. 2d at 1365.

Another glaring example is Plaintiff's reliance on studies that have found that Plavix, when taken alone, is not more effective than taking aspirin by itself. As is clear from the record, however, Mr. LaBarre took Plavix in combination with aspirin, and therefore, any evidence comparing the efficacy of aspirin taken alone and Plavix taken alone has no bearing on Plaintiff's case. Overall, Plaintiff has failed to explain how any of the studies regarding efficacy are relevant to the adequacy of the warnings with respect to Plaintiff's health condition, i.e., ACS. Thus, these studies fail to raise a genuine issue of material fact on the question of whether Plavix's warnings were adequate.

Moreover, it appears that Plaintiff's efficacy arguments are not relevant in the context of a failure-to-warn analysis. Plaintiff's claim is essentially premised on the fact that he suffered substantial bleeding as a result of taking both Plavix and aspirin at the same time - not that Plavix did not work. As the Court has previously noted, in Florida, a drug manufacturer is required to provide an adequate warning of its product if it knows of any potential harm that may result from the use of its product. In other words, a proper warning should adequately alert a physician to any danger or harm that may result from ingesting the drug. See Pinchinat v. Graco Children's Products, Inc., 390 F.

Supp. 2d 1141, 1146 (M.D. Fla. 2005)(citing Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167, 1772 (Fla. Ct. App. 1998)). Permitting Plaintiff to pursue his failure-to-warn claim on an efficacy theory would impermissibly expand liability under Florida law on the adequacy of pharmaceutical warning labels. See In re Fosamax Prods. Liab. Litig., No. 06-1789, 2010 U.S. Dist. LEXIS 33260, at * 14-15 (S.D.N.Y. Mar. 26, 2010)("To allow Plaintiff to pursue a claim for the 'failure to warn' of the efficacy of a drug would be an expansion of liability under Florida law."); see also Tobin v. Astra Pharmaceutical Prods., Inc., 993 F.2d 528, 536 (6th Cir. 1993), abrogated on other grounds by J. McIntyre Machinery, Ltd. v. Nicastro, 131 S.Ct. 2780 (2011)(finding that the plaintiff's argument regarding the efficacy of the drug, ritodrine, should not be made in the context of a failure-to-warn claim.); Neeham v. White Labs., Inc., 639 F.2d 394, 402 (7th Cir. 1981).[10]

The remaining studies and expert opinions upon which Plaintiff rely are simply not sufficient to show that the warnings regarding the risks of bleeding in patients who suffer from ACS, were inadequate at the time that Mr. LaBarre was on dual therapy. First and foremost, the warning label clearly cautions users that "PLAVIX

[10] On the issue of efficacy, Plaintiff also relies on FDA law and regulations on labeling requirements to support her failure-to-warn claim. However, her reliance is misplaced, because any violation of FDA labeling requirements is an issue of federal law, not Florida strict liability law. See, e.g., Cook v. MillerCoors, LLC., 872 F. Supp. 2d 1346 (M.D. Fla. 2012).

use with aspirin was associated with an increase in bleeding compared to placebo with aspirin. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal . . . sites." See February 2002 Plavix Labeling. In addition, the label references a table, taken from the CURE study, which publishes statistics regarding incidence of bleeding when taking Plavix and aspirin together compared to taking aspirin with a placebo (e.g., Major bleeding: 3.7% v. 2.7%). See Id., Table 3. Plaintiff does not dispute that this label, which was in effect when Mr. LaBarre was prescribed the drug, warned of the particular incidence of bleeding experienced by patients – like Mr. LaBarre – who took Plavix with aspirin. Rather, it appears that Plaintiff contends that those warnings were inaccurate.

However, Plaintiff's evidence is insufficient to establish a genuine issue of material fact on the accuracy of the warning label: aside from the evidence regarding the efficacy of Plavix – which this Court has discounted – Plaintiff fails to provide any evidence to show that the risks published on the Plavix warning label were somehow inaccurate, insofar as the warnings concern the risk of bleeding in ACS patients who take both Plavix and aspirin. Indeed, some of the medical evidence upon which Plaintiff relies indicate that when taking Plavix and aspirin in combination, there is an increased risk of bleeding, which risks are already displayed

on Plavix's warning label. For example, Plaintiff references the CHARISMA trial study which primarily compared the effectiveness of long-term treatment by patients taking Plavix plus aspirin with patients taking aspirin alone. The study concluded that "[i]n summary, the combination of clopidogrel plus aspirin was not significantly more effective than aspirin alone in reducing the rate of myocardial infraction . . . ." See Pl. Ex. 14, p. 1714. While the study went on to note that "the risk of moderate-to-severe bleeding was increased," see Id., there is no indication that the results of the study contradict those risk levels found on the Plavix warning label. In that regard, Plaintiff fails to explain how the results of the CHARISMA study undermine Plavix's published warnings. Perhaps even more crucial is the fact that the findings of the CHARISMA study were published in 2006 – more than a year **after** Mr. LaBarre stopped taking Plavix. Therefore, those findings cannot bolster Plaintiff's failure-to-warn claim since this study was not available at the time Mr. LaBarre was taking Plavix.

In addition, Plaintiff points to an email written in 1999 by Melvin Blumenthal, Executive Director for Global Clincial Development at BMS, wherein he expressed concerns regarding higher rates of bleeding when treating **stroke** patients with Plavix and aspirin at the same time. See Blumenthal Email dated February 4, 2007. In that connection, Plaintiff referenced an April 2004

email sent by Blumenthal which indicated that the outcome of the MATCH[11] study revealed that the then-Plavix warning label was relatively "weak" regarding the risks of bleeding in patients who suffered **ischemic stroke or transient ischemic attack**. See Blumenthal Email Dated April 13, 2004. Since Mr. LaBarre did not suffer a stroke at the time he was taking Plavix, this study is not relevant to show that the Plavix warning label was inaccurate regarding the risks of bleeding in patients – like Mr. LaBarre – who suffered from ACS. Furthermore, Plaintiff does not cite to any evidence or authority that links the results of the MATCH study to patients with ACS. Similarly unconvincing is the June 2005 Opinion piece published in the CHEST Journal, which highlights certain findings regarding the use of Plavix after a coronary artery bypass grafting. See Pl. Ex. 21. Importantly, Plaintiff does not explain how this article and the authors' opinion impact the accuracy of Plavix's warning label, other than to suggest that there is a risk of increased bleeding when taking Plavix and aspirin - which risk was already warned by Defendants.

Finally, the Court will discuss the opinions of Plaintiff's expert, Dr. Moye. In Dr. Moye's expert report, he opines on the

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[11] The MATCH study was conducted to compare the side effects of patients who took aspirin and Plavix after recent ischemic stroke or transient ischemic attack, with those stroke patients who took only Plavix. See Pl. Ex. 13. Because the study was not conducted with patients who suffer from ACS, I need not detail the specifics of the MATCH study as it is not material to the facts in this case.

efficacy of Plavix taken by patients with ACS. See Dr. Moye's Report p. 1. Essentially, it is his opinion that due to the risks of increased bleeding and low efficacy of Plavix in certain populations of patients, there is no special benefit from prescribing Plavix to those patients. Id. The expert goes on to explain certain studies preformed on Plavix, some of which were sponsored by Defendants, e.g., CAPRIE, CURE and CREDO. His ultimate conclusions were derived from the analyses of those studies. Of particular relevance, Plaintiff argues that Dr. Moye has opined that Plavix is not effective when taken long term; that "identifying the optimal duration of the Plavix/[aspirin] effect is an important public health issue in the management of ischemic heart disease." Id. at p. 43-44. However, lacking in Dr. Moye's report is any conclusion as to how his opinions affect Mr. LaBarre's Plavix prescription, or how Plavix's warning label should have reflected the duration of therapy and the impact of a long term therapy on the risk of increased bleeding.

Moreover, Plaintiff suggests that Defendants should have warned that Plavix is not effective for non-smokers. Plaintiff's own evidence does not directly show that Plavix is ineffective on non-smokers. See Pl. Ex. 40, p. 2496 (clinical study noted that the "influence of smoking status on clopidogrel metabolism is currently being evaluated in a prospective study.") And, Dr. Moye's report only states that the effect of Plavix "in nonsmokers depends

on the circumstances. In those indications where Plavix has a demonstrable effect, the effect in nonsmokers is also non-negative. However, in patients in whom Plavix is relatively non-effective, representing most of the patient population, Plavix remains ineffective in smokers." Dr. Moye's Report, p. 46. Clearly, this broad statement does not stand for the proposition that Plavix is not effective for non-smoking patients. Thus, the Court finds that Plaintiff has not presented sufficient evidence to show that there is a genuine issue of material fact that Plavix's warning label was inaccurate.

In sum, on the issue of the accuracy of Plavix's warning label, Plaintiff presents a number of studies and articles which are neither relevant nor probative in demonstrating that the warnings regarding the risks of increased bleeding in ACS patients taking Plavix and aspirin were inaccurate in any way. Significantly, other than Dr. Moye's opinions, which do not explicitly state that the Plavix warning labels were inadequate or inaccurate, Plaintiff has not presented any other expert testimony. Based on this reason alone, Plaintiff's failure-to-warn claim fails under Florida Law. Overall, Plaintiff fails, on this motion, to adduce any relevant or credible evidence to show that Plavix's warning labels are somehow inaccurate, and therefore, she fails to establish the first prong of the failure-to-warn claim.

B. Causation

Because Plaintiff has not demonstrated on this motion that the Plavix warnings were inadequate, the Court need not examine the next prong of a failure-to-warn claim, i.e., that the inadequacy of the warnings proximately caused the complained-of injury. Nonetheless, the Court also finds that Plaintiff has failed to raise a genuine issue of material fact as to causation.

The cardiologist, Dr. Craven, testified that he placed Mr. LaBarre on Plavix and aspirin in 2003 and 2004 because of severe complications related to Mr. LaBarre's ACS. See Craven Dep., T56:21-57:18. In so doing, Dr. Craven recognized that there was a substantial risk of bleeding in connection with placing Mr. LaBarre on dual therapy. See Id. at T61:6-62:20. It was clear from Dr. Craven's testimony that despite the risk, he considered Plavix as the appropriate treatment for Mr. LaBarre's condition. In fact, Dr. Craven explained that without Plavix, Mr. LaBarre would have suffered myocardial infarction or congestive heart failure, both of which would have led to death. Id. at T56:21-57:18. Most importantly, Dr. Craven affirmatively stated that even knowing that Mr. LaBarre died of a subdural hematoma, the doctor continues to believe that Plavix was the proper medication. Id. at T95:24-96:13.[12]

[12] Plaintiff asserts that Dr. Craven's testimony should be given less weight because the doctor, at one point in time, was paid by BMS as a speaker and there is a question of bias on his

Likewise, Plaintiff's treating physician, Dr. Bailey, echoes Dr. Craven's opinions. Indeed, Dr. Bailey was well aware of the risk of bleeding when prescribing Plavix and aspirin to her patients. See Dr. Bailey's Dep., T90:15-24; T94:16-95:5. Knowing that risk, the doctor decided to put Mr. LaBarre on Plavix because the benefits of that drug outweighed its risks. See Id. at T92:9-14; T116:24-117:8; T134:6-13. Dr. Bailey concluded in her deposition that even today knowing the information presented to her by Plaintiff, she would not "second-guess" her decision to prescribe Plavix for Mr. LaBarre. See Id. at T136:11-17. Indeed, the opinions of both doctors were unequivocal: because the medical benefits for Mr. LaBarre's condition outweighed the risks, the physicians were confident that the treatment they had provided for their patient was medically necessary and appropriate. More to the point, Drs. Craven and Bailey both represented that they would have not changed their prescription for Mr. LaBarre even understanding the additional risks or questions of efficacy Plaintiff has raised in this litigation. Accordingly, because there is no causation evidence to support Plaintiff's failure-to- warn claim, this claim is dismissed.

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part. However, bias, if any, on Dr. Craven's part, would not change the result here because, as the Court will discuss below, Mr. LaBarre's treating physician, Dr. Bailey, also agrees with Dr. Craven's medical opinion that dural therapy was the appropriate medical treatment for Mr. LaBarre.

III. Florida Defective Design Claim

Plaintiff concedes that Florida, which has adopted Comment K of Section 402A of the Restatement (Second) of Torts, precludes a design defect claim when the "the product's benefits . . . outweigh its known risks as of the date of the product is distributed." Adams v. G.D. Searle & Co., 576 So.2d 728, 733 (Fla. Ct. App. 1991). In other words, so long as a product is accompanied by proper directions and warnings, Plaintiff cannot pursue the theory of defective design. See Amore v. G.D. Searle & Co., 748 F. Supp. 845, 853 (S.D. Fla. 1990). Therefore, having already determined that Plaintiff is unable to establish any triable issue with respect to her failure-to-warn claim, Plaintiff's design claim correspondingly fails.

IV. Florida Manufacturing Defect Claim

To recover on a manufacturing defect claim, Plaintiff must produce sufficient evidence on this motion to show that a mistake in the manufacturing process occurred. See Harduvel v. Gen. Dynamics Corp., 878 F.2d 1311, 1317 (11th Cir. 1989); see also Cook v. Smith, No. 04-1116, 2006 WL 580991, at *2 (M.D. Fla. Mar. 8, 2006)(no manufacturing defect under Florida law because plaintiff offered "neither evidence nor argument to support a claim that any alleged defect occurred during manufacture of the [product]."). Here, no such evidence has been adduced by Plaintiff. Indeed, the genesis of Plaintiff's complaints about Plavix is the drug's anti-

platelet properties, which allegedly caused him to suffer injuries related to massive bleeding. Those anti-clotting properties are the intended effects of Plavix, and therefore, by Plaintiff's own allegations, the nature of her claim is not premised on whether the drug deviated from the construction or specifications of Plavix. Without any evidence showing that Plavix was defectively manufactured, this claim is dismissed.

V. Negligence Claim

Plaintiff's negligence claim is nothing more than a restatement of her defective design, defective manufacturing, and failure-to-warn claims. Plaintiff avers that Defendants "negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and/or sold Plavix." Am. Comp., ¶ 65. Because the Court has found that none of her claims have merit, this claim necessarily fails.

VI. Discovery Request Pursuant to Rule 56(d)

Finally, Plaintiff seeks additional discovery pursuant to Fed. R. Civ. P. 56(d). Based on the Court's ruling herein, there is no basis to provide Plaintiff additional opportunities to seek discovery. Much of what Plaintiff proposes to seek relates to Plavix's effectiveness, which I have found to be neither relevant nor probative of Plaintiff's claims. Also, Plaintiff has had the opportunity to take the depositions of Mr. LaBarre's treating physicians. As the Court has already found that these physicians'

testimonies do not support Plaintiff's claim in light of the learned intermediary doctrine, additional discovery would not likely lead Plaintiff to any new evidence that would change the results here. Accordingly, the Court rejects Plaintiff's position that the motion is premature and further discovery should be taken.

CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted in its entirety. As a result, Plaintiff's Amended Complaint is dismissed.

An appropriate Order shall issue.

Dated: January 11, 2012

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge